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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,014	09/15/2003	Achim H. Krauss	17619 (AP)	1736

7590
Robert J. Baran (T2-7H)
ALLERGAN, INC.
Legal Department
2525 Dupont Drive
Irvine, CA 92612

02/07/2008

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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02/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/663,014

Applicant(s)

KRAUSS, ACHIM H.

Examiner

Lakshmi S. Channavajjala

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11-15-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and response all dated 11-15-07 is acknowledged.

Claims 12-17 are newly added. Claims 1-10 and 12-17 are pending.

The following is a new rejection in view of the amendment:

Instant claims now require a method of converting gray hair of the "beard or scalp" to the original pigment in hair follicles of a human by administering a compound represented by formula I.

1. Claim 16 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
2. Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 14. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claim 1-10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article New drugs of 2001 (J Amer. Pharm. Association 2002) in view of US 5,290,562 ('562, cited in previous actions of record).

The above article entitled "new Drugs of 2001" discloses two new drugs for glaucoma, bimatoprost and travoprost of which the former is within the scope of the instant claims (see claim 4). The article teaches that the compound bimatoprost is useful in reducing the intraocular pressure (page 2). However, the side effects of the compound included among others, darkening of eyelashes, eyelash growth and pigmentation (page 3). Thus, the compound of the instant invention is known for increasing the pigmentation and darkening of hairs (eye lashes). The article also teaches 0.3% bimatoprost (claim 2) as a solution (claim 9). While the above article fails to teach the claimed method per se, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ bimatoprost for increasing pigmentation or darkening hair (eyelash or beard or scalp hair) because the compound bimatoprost is known to increase pigmentation.

A careful review of the instant specification on page 7, lines 10-18 states:
"As used herein, gray hair includes hair associated with the scalp, eyebrows, eyelids, beard, and other areas of the skin of animals, e.g. humans". Thus, the ability of bimatoprost in converting gray hair to original pigment is not dependent upon on the hair

location (beard or scalp or eyelash). The above article fails to teach various routes of administration claimed in the dependent claims.

'562 teach a method of increasing melanin formation on the skin or scalp by administering a melanin synthesis promoting or a pigmenting compound i.e., a tyrosine or its derivative. '562 teach that increasing the melanin synthesis in the skin damaged by UV radiation can be induced by melanin synthesizing compounds (co1.1-2) and that the pigment activity is also increased in the scalp. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition containing bimatoprost of "new drugs 2001" article for retarding the appearance of grey hair in a mammal in need thereof because '562 teaches that increasing or stimulating melanin synthesis improves the retardation of grey hair together with increasing the melanin pigment. Further, in the absence of any criticality, choosing a particular route of administration of bimatoprost so as to achieve the desired pigmentation would have been within the scope of a skilled artisan.

Response to Arguments

Applicant's arguments filed 11-15-07 have been fully considered but they are not persuasive.

Applicants' arguments with respect to the Ortonne are moot because the reference is no longer applied in the instant rejection.

With respect to the arguments regarding the reference teaching bimatoprost, applicants' argue that bimatoprost is not a prostaglandin. However, instant rejection does not

equate bimatoprost to the other prostaglandins. Applicants argue that only that bimatoprost causes darkening of eyelashes but not scalp or beard and that the eyelashes are not equivalent to hair on scalp. However, a careful review of the instant specification on page 7, lines 10-18 states:

"As used herein, gray hair includes hair associated with the scalp, eyebrows, eyelids, beard, and other areas of the skin of animals, e.g. humans". Thus, the ability of bimatoprost in converting gray hair to original pigment is not dependent upon on the hair location (beard or scalp or eyelash). Accordingly, bimatoprost possess the ability to darken eyelashes and also the hair on scalp or beard.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi Channavajjala/

Primary Examiner

AU 1611
February 2, 2008